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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/506,805

01/19/2005

Andrew Lennard Lewis

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EXAMINER

PURDY, KYLE A

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

04/21/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,805	<b>Applicant(s)</b> LEWIS ET AL.	
	<b>Examiner</b> Kyle Purdy	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,7-16,20-35,38 and 42-60 is/are pending in the application.
- 4a) Of the above claim(s) 29-35 and 45-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-16,20-28,38,42-44 and 57-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Exhibit A</u> .                        |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/20/2009 has been entered.

### ***Status of Application***

2. The Examiner acknowledges receipt of the amendments filed on 02/20/2009 wherein claims 57-60 are newly added and claims 5 and 6 have been cancelled.

3. Claims 1, 7-16, 20-28, 38, 42-44 and 57-60 are presented for examination on the merits. Claims 29-35 and 45-56 stand as withdrawn. The following rejections are made.

### ***Response to Applicants' Arguments***

4. Applicants arguments filed 02/20/2009 regarding the rejection of claims 5 and 6 made by the Examiner under 35 USC 103(a) over Lobb et al. (J. Am. Chem. Soc., 2001) in view of Kataoka et al. (Adv. Drug Delivery Rev., 2001), evidenced by Dalmark et al. (J. Gen. Physiol., 1981) have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of the claims.

5. Applicants arguments filed 02/20/2009 regarding the rejection of claims 1, 7-16, 21-28, 38, 43 and 44 made by the Examiner under 35 USC 103(a) over Lobb et al. in view of Kataoka et al., evidenced by Dalmark et al. have been fully considered but they are not found persuasive.

6. The rejection of claims 1, 7-16, 21-28, 38, 43 and 44 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 10/20/2008.

7. In regards to the 103(a) rejection, Applicant asserts the following:

**A)** Dalmark does not disclose that doxorubicin has a partition coefficient between octanol and water of at least 1.5;

**B)** The teaching of Lobb has been misinterpreted, fibrinogen as a drug compound with a partition coefficient of at least 1.5; and

**C)** It would not be obvious to combine the teachings of Lobb and Kataoka as set forth in the office action because the block copolymers of Kataoka are all polyethylene glycol based, rather than MPC based as required by Lobb.

8. In response to A, the Examiner respectfully disagrees. Buffers are commonly used in determining the partition coefficient for a given compounds between octanol and water. Buffers are commonly employed in octanol-water partition coefficient calculations. According to the EPA (see Exhibit A), partition coefficients are to be determined when the compound is in a non-ionized state sometimes buffers are required to prevent ionization (see page 2, (ii)). As it's known the doxorubicin has two ionizable functionalities, one with a pKa of 7.5 and the other with a pKa of 9.5, a pH of 7.3 would effectively prevent the compound from ionizing. See Dalmark, page 350. As buffers are commonly used in partition coefficient calculations there is no reason to believe TRIS presence in the aqueous phase would impact the resultant value, especially in view of the EPA supporting its use for the accurate coefficient measurement of the compound. Applicants arguments are not found persuasive.

9. In response to B, the Examiner respectfully disagrees. The Examiner acknowledges stating that fibrinogen is a biologically active molecule associated with the micelle, however the Examiner is not relying on this to obviate the present claims. Lobb has not been misinterpreted.

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The Examiner clearly states on the record that Lobb fails to teach their nanoparticles “as having a hydrophobic drug associated with the core” wherein the drug has a partition coefficient of at least 1.5. See page 5, paragraph 13 of the action mailed on 10/20/2008. Applicants argument is not found persuasive.

10. In response to C, it's duly noted that Lobb teaches different polymers from that of Kataoka. However, this does not preclude their combination. Lobbs teaches amphiphilic copolymers that form micelles wherein the hydrophilic portion of the copolymer is present on the outer surface of the micelle and the hydrophobic portion is present in the core of the micelle when present in aqueous systems. Lobb teaches that these micelles have substantial promise in drug delivery applications, but fails to expand on such promise. Kataoka is relied upon for the showing that block amphiphilic copolymer micelles, like those taught by Lobb (structurally), are commonly employed in drug delivery systems, and are especially useful for the delivery of hydrophobic drugs such as doxorubicin. Thus, based upon the suggestion by Lobb that their nanoparticles have substantial promise for applications in drug delivery, any person of ordinary skill in the art would look to the art for teachings centered around using amphiphilic micelles for the delivery of drugs. If such a result were the combination of Lobb and Kataoka to arrive at a composition as presently claimed, then such a result would be a product of ordinary skill and common sense, not one off innovation. Applicants argument is not found persuasive.

11. Applicants arguments filed 02/20/2009 regarding the rejection of claims 20 and 42 made by the Examiner under 35 USC 103(a) over Lobb et al. in view of Kataoka et al. and Coessens et al. (Prog. Polym. Sci, 2001), evidenced by Dalmark et al. have been fully considered but they are not found persuasive.

12. The rejection of claims 20 and 42 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 10/20/2008.

13. In regards to the 103(a) rejection, Applicant asserts the following:

**D)** The rejection is moot in view of the amendment to the claims.

14. In response to D, the Examiner is unclear about the amendment which Applicant is referring to. None of claims 20, 42 and the claims from which they depend are currently listed as being amended, or are even indicative of being amended. Thus, the Examiner cannot fully respond to Applicants arguments.

**Maintained Rejection, of record**  
***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

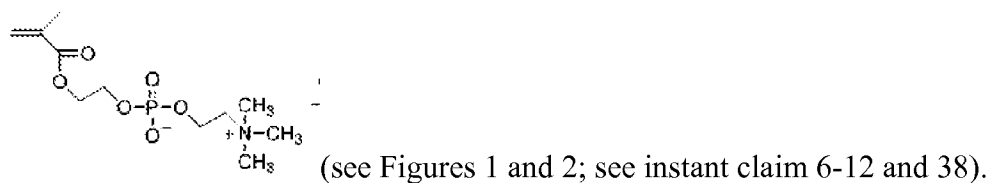
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. **Claims 1, 7-16, 21-28, 38, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobb et al. (J. Am. Chem. Soc., 2001, 123, 7913-7914; of record) in view of Kataoka et al. (Adv. Drug Delivery Rev., 2001, 47(1), 113-131; of record), evidenced by Dalmark et al. (J. Gen. Physiol, 1981, 78, 349-364; of record).**

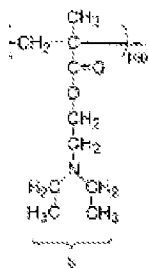
17. Lobb discloses the synthesis of a biocompatible phosphrylcholine-based methacrylate copolymer. The copolymer is an amphiphilic block copolymer having a hydrophilic block and in the solution, and a biologically active compound associated with the polymer [fibrinogen] (see

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page 7914, left column 2<sup>nd</sup> paragraph; see instant claim 1), wherein the hydrophilic block has pendant zwitterionic groups (see Figure 2; structure; see instant claim 1). The copolymer is in the form of micelles (see Figure 2, 'DEA core micelles'; see instant claim 1). The hydrophilic block is formed by radical polymerization of the ethylenically unsaturated monomers (see page 7913, left column, 2nd paragraph; see instant claim 1). The hydrophilic monomers comprise a zwitterionic monomer having the following structure:



18. The hydrophobic block comprises a pendant group which is ionizable and possesses a pKa or pKb in the range of 4 to 10 (see Figure 2, structure). The hydrophobic structure is shown below:



19. The pKa for the hydrophobic structure is 9.17 (see STN search of structure b; see instant claim 13). The hydrophobic block is polymerized by radical polymerization of the ethylenically unsaturated monomers (see page 7914, left column, 4<sup>th</sup> paragraph; see instant claim 14). The degree of polymerization for the hydrophilic block is 30 (see Figure 2, structure; see instant claims 21 and 43) and the degree of polymerization for the hydrophobic block is 100 (see Figure

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2, structure; see instant claims 22 and 44). The ratio for the degrees of polymerization is 10:3 which falls within the range of 1:5 to 10:1 (see Figure 2, structure; see instant claim 23). The polymerization process for polymerizing the hydrophilic block is via atom transfer radical polymerization (see page 7913, left column, 2nd paragraph; see instant claims 24-25). Lobb teaches that the atom transfer radical polymerization initiator is that of oligo(ethylene glycol) bromide (OEGBr). OEGBr is a hydrophobic polymer compound and is taught to be used for the synthesis of the MPC homopolymer (see page 7913, right column, 2<sup>nd</sup> paragraph; see instant claim 26). It is also taught that that MPC diblock copolymers can also be synthesized via atom transfer radical polymerization (see page 7914, left column, 4<sup>th</sup> paragraph; see instant claims 24 and 25). Moreover, Lobb suggests that the polymeric micelles are highly biocompatible and show considerable promise for drug delivery applications (see 7914, right column).

20. Lobb fails to specifically teach the species of diisopropylamino ethyl phosphate inner salt. Lobb also fails to teach the nanoparticle as having a hydrophobic drug associated with the core of the nanoparticle, said drug having a partition coefficient between octanol and water of at least 1.5.

21. Kataoka is a review article directed to block copolymer micelles and their use in local drug delivery. In the abstract it is taught that block copolymers are useful because of the fact that the outer hydrophilic surface can be functionalized to optimize its physiochemical and biological properties whereas the inner hydrophobic core is useful as a functioning reservoir for a variety of diverse drugs. It is also taught that much interest has been directed to loading nanoparticles with drugs because of the relatively high loading capacity of the inner core (see page 114, left column.) In section 2, an example of an amphiphilic copolymer micelle is taught

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wherein the micelles hydrophobic core houses the cytotoxic drug doxorubicin (see page 115).

Doxrubicin has a partition coefficient between water and octanol of 1.9 (see Dalmark et al., page 356; see instant claim 1) It is taught that significant pi-pi interactions contribute substantially to increasing the cohesive force in the core which stabilizes the physically entrapped drug (see page 116, left column).

22. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lobb and Kataoka with a reasonable expectation for success in arriving at a composition comprising an amphiphilic copolymer having a zwitterionic group which has a biologically active, cytotoxic molecule with a partition coefficient of at least 1.5 sequestered in the core of the micelle. One would have been motivated to substitute diisopropylamino ethyl methacrylate for (diethylamino)ethyl methacrylate because the two monomers only differ by the presence of a methyl group. The presence of a methyl group in place of a hydrogen does not give patentable momentum to the recited species. It is well established that a methyl is structurally analogous to a hydrogen, and absent any secondary result, the elected species would possess the same functional properties as that of diethylammonium. With respect to including the drug within in the core of the particle, this is also obvious. Kataoka specifically teaches that loading hydrophobic cytotoxic drugs which have a partition coefficient of at least 1.5 into their core is a common practice in the art of amphiphilic micelles. One would be motivated to employ the structure discussed by Kataoka because of the ability to achieve high loading of drug into the particle which means high localized dosages to the patient. Moreover, by loading the drug into the core of the micelle, the drugs rate of release will be controlled and the drug will provided a thermodynamically stable environment. With

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respect to the requirement that the copolymer be synthesized by an initiator (e.g. OEGBr) possessing a hydrophobic polymer moiety is also obvious, as it is specifically suggested by Lobb. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

23. Note, Dalmark is cited as to show that doxorubicin has a partition coefficient between octanol and water of at least 1.5.

**24. Claims 20 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobb et al. (J. Am. Chem. Soc., 2001, 123, 7913-7914; of record) in view of Kataoka et al. (Adv. Drug Delivery Rev., 2001, 47(1), 113-131) and Coessens et al. (Prog. Poly. Sci., 2001, 26, 337-377; of record), evidenced by Dalmark et al. (J. Gen. Physiol, 1981, 78, 349-364).**

25. Lobb, Kataoka and Dalmark are relied upon for disclosure described in the rejection of claim 1 under 35 U.S.C. 103(a).

26. Lobb teaches that the polydispersity of the MPC homopolymer block is from between 1.23 to 1.45 (see page 7914, left column, 2<sup>nd</sup> paragraph).

27. Lobb, Kataoka and Dalmark fail to teach the polydispersity for the hydrophobic block of the copolymer.

28. Coessens cures this deficiency. Coessens is drawn to describing in detail the properties generally associated with atom transfer radical polymerization process, teaches that atom transfer radical polymerization creates well-defined, precisely controlled polymers with polydispersities generally lower than 1.3 (see Coessens, page 339, last paragraph).

29. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lobb, Kataoka, Coessens and Dalmark with a reasonable expectation for success in arriving at a composition comprising an amphiphilic block copolymer having a hydrophilic and a hydrophobic block, dispersed in solution, and a biologically active compound associated with the polymer, wherein the hydrophilic block as pendant zwitterionic groups wherein the polydispersity of molecular weight of each block is from 1.1 to 1.4. Although Lobb is silent to the polydispersity of the hydrophobic block, the block if synthesized by atom transfer radical polymerization would quite likely have a polydispersity less than 1.3. Therefore, the invention as a whole is *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

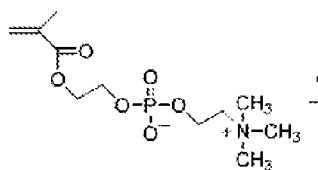
**New Rejections, Necessitated by Amendment**  
***Claim Rejections - 35 USC § 103***

**30. Claims 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lobb et al. (J. Am. Chem. Soc., 2001, 123, 7913-7914; of record) in view of Kataoka et al. (Adv. Drug Delivery Rev., 2001, 47(1), 113-131; of record), evidenced by Dalmark et al. (J. Gen. Physiol, 1981, 78, 349-364; of record).**

31. Lobb discloses the synthesis of a biocompatible phosphorylcholine-based methacrylate copolymer. The copolymer is an amphiphilic block copolymer having a hydrophilic block and in the solution, and a biologically active compound associated with the polymer [fibrinogen] (see page 7914, left column 2<sup>nd</sup> paragraph; see instant claim 57 and 58), wherein the hydrophilic block has pendant zwitterionic groups (see Figure 2; structure; see instant claim 57 and 58). The

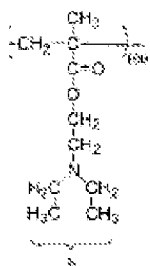
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copolymer is in the form of micelles (see Figure 2, 'DEA core micelles'). The hydrophilic block is formed by radical polymerization of the ethylenically unsaturated monomers (see page 7913, left column, 2nd paragraph; see instant claims 57 and 58). The hydrophilic monomers comprise a zwitterionic monomer having the following structure:



(see Figures 1 and 2; see instant claims 57 and 58).

32. The hydrophobic block comprises a pendant group which is ionizable and possesses a pKa or pKb in the range of 4 to 10 (see Figure 2, structure; see instant claim 58). The hydrophobic structure is shown below:



33. The pKa for the hydrophobic structure is 9.17 (see STN search of structure b). The hydrophobic block is polymerized by radical polymerization of the ethylenically unsaturated monomers (see page 7914, left column, 4<sup>th</sup> paragraph; see instant claims 57 and 58). The degree of polymerization for the hydrophilic block is 30 (see Figure 2, structure; see instant claims 21 and 43) and the degree of polymerization for the hydrophobic block is 100 (see Figure 2, structure; see instant claim 58). The ratio for the degrees of polymerization is 10:3 which falls within the range of 1:5 to 10:1 (see Figure 2, structure; see instant claim 58). The

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polymerization process for polymerizing the hydrophilic block is via atom transfer radical polymerization (see page 7913, left column, 2nd paragraph; see instant claims 57 and 58). Lobb teaches that the atom transfer radical polymerization initiator is that of oligo(ethylene glycol) bromide (OEGBr). OEGBr is a hydrophobic polymer compound and is taught to be used for the synthesis of the MPC homopolymer (see page 7913, right column, 2<sup>nd</sup> paragraph; see instant claim 26). It is also taught that that MPC diblock copolymers can also be synthesized via atom transfer radical polymerization (see page 7914, left column, 4<sup>th</sup> paragraph; see instant claims 57 and 58). Moreover, Lobb suggests that the polymeric micelles are highly biocompatible and show considerable promise for drug delivery applications (see 7914, right column).

34. Lobb fails to specifically teach the species of diisopropylamino ethyl phosphate inner salt (instantly elected compound). Lobb also fails to teach the nanoparticle as having a hydrophobic cytotoxic drug associated with the core of the nanoparticle, said drug having a partition coefficient between octanol and water of at least 1.5.

35. Kataoka is a review article directed to block copolymer micelles and their use in local drug delivery. In the abstract it is taught that block copolymers are useful because of the fact that the outer hydrophilic surface can be functionalized to optimize its physiochemical and biological properties whereas the inner hydrophobic core is useful as a functioning reservoir for a variety of diverse drugs. It is also taught that much interest has been directed to loading nanoparticles with drugs because of the relatively high loading capacity of the inner core (see page 114, left column.) In section 2, an example of an amphiphilic copolymer micelle is taught wherein the micelles hydrophobic core houses the cytotoxic drug doxorubicin (see page 115). Doxorubicin has a partition coefficient between water and octanol of 1.9 (see Dalmark et al., page

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356; see instant claims 47-60) It is taught that significant pi-pi interactions contribute substantially to increasing the cohesive force in the core which stabilizes the physically entrapped drug (see page 116, left column).

36. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lobb and Kataoka with a reasonable expectation for success in arriving at a composition comprising an amphiphilic copolymer having a zwitterionic group which has a biologically active, cytotoxic molecule with a partition coefficient of at least 1.5 sequestered in the core of the micelle. One would have been motivated to substitute diisopropylamino ethyl methacrylate for (diethylamino)ethyl methacrylate because the two monomers only differ by the presence of a methyl group. The presence of a methyl group in place of a hydrogen does not give patentable momentum to the recited species. It is well established that a methyl is structurally analogous to a hydrogen, and absent any secondary result, the elected species would possess the same functional properties as that of diethylammonium. With respect to including the drug within in the core of the particle, this is also obvious. Kataoka specifically teaches that loading hydrophobic cytotoxic drugs which have a partition coefficient of at least 1.5 into their core is a common practice in the art of amphiphilic micelles. One would be motivated to employ the structure discussed by Kataoka because of the ability to achieve high loading of drug into the particle which means high localized dosages to the patient. Moreover, by loading the drug into the core of the micelle, the drugs rate of release will be controlled and the drug will provided a thermodynamically stable environment. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the

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time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

37. Note, Dalmark is cited as to show that doxorubicin has a partition coefficient between octanol and water of at least 1.5.

### ***Conclusion***

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

40. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/  
Examiner, Art Unit 1611  
April 20, 2009*

*/David J Blanchard/  
Primary Examiner, Art Unit 1643*